UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re ELAN CORPORATION SECURITIES LITIGATION	:	Master File No. 1:08-cv-08761-AKH
This Document Relates To: ALL ACTIONS.	:	

PLAINTIFFS' MEMORANDUM OF LAW
IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

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STATUTES, RULES AND REGULATIONS

In this class action for violation of the anti-fraud provisions of the federal securities laws,[1] Lead Plaintiff The Council of the Borough of South Tyneside Acting in Its Capacity as the Administering Authority of the Tyne & Wear Pension Fund and Plaintiff Plumbers & Steamfitters Local 773 Pension Fund (together, "Plaintiffs") respectfully submit this memorandum of law in opposition to the Motion to Dismiss the Consolidated Complaint, dated December 11, 2009, filed by defendants Elan Corporation, plc ("Elan" and, together with non-defendant Wyeth, the "Companies"), G. Kelly Martin, and Lars Ekman (collectively, "Defendants").[2] Plaintiffs bring this action on behalf of all purchasers of Elan's publicly-traded stock or American Depository Receipts ("ADRs") between May 21, 2007 and October 21, 2008 (the "Class Period").[3]

I. INTRODUCTION

This securities class action concerns misrepresentations that Defendants made about the results of a safety and efficacy trial for a drug called bapineuzumab, also known as AAB-001, that Elan was developing with the pharmaceutical company Wyeth for the treatment of Alzheimer's disease. ¶¶1-2.

In late 2006 and early 2007, before the Class Period, Elan and Wyeth represented that they might proceed to Phase 3 clinical testing of bapineuzumab in the first half of 2007, before the completion of Phase 2 testing, but only if the results of an interim look at the Phase 2 data satisfied certain "***very specific criteria***" relating to "four different clinical ***endpoints*** [objectives] to the trial,

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[1] *See* §§10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§78j(b) and 78t(a), and Rule 10b-5, 17 C.F.R. §240.10b-5, promulgated thereunder.

[2] "Individual Defendants" shall refer to Defendants Martin and Ekman.

[3] As used herein, "Complaint" shall refer to the Consolidated Complaint for Violations of the Federal Securities Laws, dated August 17, 2009. "¶__" and "¶¶__-__" shall refer to paragraphs in the Complaint.

cognition, memory, quality of life and imaging." ¶37.[4] Those criteria were measured by the ADAS-cog and DAD cognitive tests used in the review. ¶34. If bapineuzumab met those criteria, the interim-look data would be considered "***spectacular***," "***strong***," and "***very meaningful***." ¶¶6, 36, 37. Defendants represented that they, unlike other pharmaceutical companies, would ***not*** move forward to Phase 3 testing on the basis of merely "circumstantial evidence of efficacy." ¶37. They led the investing public to believe, in other words, that they would proceed to early Phase 3 testing only in the ***highly particularized circumstance*** that the Phase 2 interim look demonstrated that the study endpoints were being met.

Nonetheless, when Defendants announced, on May 21, 2007, that they were proceeding to Phase 3 testing, they declined to reveal any information concerning the results of their interim look at the Phase 2 data. Using the "blinded" nature of the Phase 2 trial as an excuse (*see* ¶39), they failed to reveal (as discussed in more detail below) that they were proceeding to Phase 3 in the ***absence*** of data that satisfied the Companies' "very specific criteria" – the prerequisites to Phase 3 testing they had identified only months before. As the reaction of the market made clear, however, investors believed that those prerequisites ***had*** been satisfied. In the wake of the Companies' announcement, the price of Elan's ADRs rose from $16.60 on the previous trading day to $18.69 on May 21, 2007, a 12.5% one-day increase. ¶40. Moreover, according to a Davy Research analyst report issued on May 21: "No data have been disclosed, ***but both companies previously outlined that results from the Phase II interim analyses would need to be 'spectacular' to proceed***." ¶41.

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[4] Unless otherwise noted, all emphasis in quotations throughout this memorandum is added.

Throughout the Class Period, Defendants continued to encourage the investing public to believe that bapineuzumab had satisfied the Companies' stringent requirements for proceeding to Phase 3 clinical testing:

- On July 26, 2007, approximately two months after the Companies announced their decision to commence early Phase 3 testing, Elan cited the interim look at Phase 2 data as a seminal basis for moving forward with Phase 3. According to defendant Ekman:[5] "The decision to move into Phase III was based on the totality of what the companies have learned from our Alzheimer's immuno therapy programs, ***including the scheduled interim look at data from our ongoing Phase II study***. . . ." ¶44.

- Five days later, on July 31, 2007, Natixis Bleichroeder published an analyst report reflecting the market's general understanding – or misunderstanding – of the message Defendants were communicating: "We think the data at the interim look must have been profound and possibly involved a continual separation of drug from placebo over time – indicative of true disease modification." ¶42.

- During a presentation on May 1, 2008, ***after*** the Phase 2 study was completed, defendant Martin[6] continued to use the word "spectacular" – a word the market had long remembered since its first use in 2006 (*see* ¶36) – stating that there continued to be **"**some ***probability***" that "***spectacular***" Phase 2 data could create a "***regulatory pathway to a filing that would be earlier than a full normal completion of Phase III.***" ¶46.

- During the same presentation, Martin skirted questions about the specific results of the Phase 2 interim review, while prompting the market to assume the very best about that data: "***once you see the Phase II data, the marketplace and the investigators, the clinicians and everyone else who wants to look at it would say, geez, I understand exactly why Wyeth and Elan started a Phase III [clinical trial when] they did***." *Id.*

- Martin stated, further: "So, without answering that specifically, I think it will be – ***it should be obvious why we moved to Phase III*** and I think that whether its statistical significance in all or parts, supported by trends, or trends with different combinations of data points. I think that the reason we moved to Phase III was ***we clearly saw***

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[5] Ekman was Elan's President of Research and Development during the Class Period until December 31, 2007, and was a member of the Board of Directors and Chairman of the Science and Technology Committee of the Board throughout the Class Period. ¶26.

[6] Martin was Elan's President and CEO at all relevant times. ¶25

> ***enough data to move forward. It's a huge decision for us, and for Wyeth and [it's] one that we don't take lightly***." *Id.*

The market remained under the illusion of exceptional prospects for bapineuzumab – sending the stock price up more than 10% upon Defendants' selective release of positive news from the Phase 2 testing on June 17, 2008 (*see* ¶¶50-51) – until Defendants released the full results on July 29, 2008. Those results showed that there was no dose response in the study, meaning that patients taking higher doses of bapineuzumab did not perform better than those taking lower doses. Further, higher doses of the drug were associated with serious side effects, including vasogenic edema, a potentially dangerous accumulation of fluid in the brain. ¶7. Upon the disclosure of the full results, including numerous other shortcomings and limitations of bapineuzumab Defendants had previously withheld (*see* ¶65), the price of Elan's ADRs plunged 42% in one day, as the artificial inflation came out of the stock price.[7] ¶66. Finally, on October 22, 2008, the public learned that European regulators had requested that the European Phase 3 trials of bapineuzumab be delayed following the disappointing results of the Phase 2 study. ¶78. With this news, the remainder of the artificial inflation in Elan's stock price evaporated, sending the price down another 13%, to close at $7.82 per ADR (¶79) – a far cry from the Class Period high of $36.82. ¶16.

Thus, the investing public was deceived into believing, throughout the Class Period, that the data from the Companies' Phase 2 testing were much stronger than they actually were. As discussed below, none of Defendants' arguments on their motion to dismiss – which boil down to a claim that their representations were true and that they had no scienter – is meritorious.

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[7] On September 29, 2009, Elan announced that it had received a subpoena from the Securities and Exchange Commission (the "SEC") requesting records and information relating to, among other things, "the July 29, 2008 announcement at the International Conference of Alzheimer's Disease concerning the Phase 2 trial data for bapineuzumab." *See* Exhibit 1 to the Declaration of Mark T. Millkey, dated February 16, 2010 ("Millkey Decl."), at 2.

II. STATEMENT OF FACTS

Elan is a neuroscience-based biotechnology company. ¶2. Although Elan's biggest-selling drug during the Class Period was Tysabri, a treatment for multiple sclerosis (¶¶2, 85), Tysabri's future was threatened when it was removed from the market in February 2005 after two patients taking it died from a rare neurological disorder. ¶2. Tysabri was back on the market by September 2006, but it was subject to a rigorous program of monitoring for further side effects. *Id.* By the start of the Class Period, sales of Tysabri had only slowly begun to recover. *Id.* At the same time, the sales of a number of Elan's other drugs were plummeting due to generic competition. ¶¶2, 85. As a result, Elan's future hinged on the safety and effectiveness of bapineuzumab (AAB-001), a drug Elan was developing with Wyeth for the treatment of Alzheimer's disease.[8] ¶2. According to the Associated Press, Elan was "banking on an Alzheimer's breakthrough for its future growth." *Id.*

Because Alzheimer's currently affects more than five million people in the United States alone,[9] the demand for a safe and effective treatment is enormous. ¶3. Current treatments reduce the symptoms of the disease, but they are not "disease modifying" – that is, they do not slow, stop, or reverse its progression. *Id.* For that reason, among others, some analysts have estimated that only 35% of Alzheimer's patients in developed countries worldwide are on medication for the condition – meaning that there is a huge and lucrative market for a disease-modifying treatment of Alzheimer's. *Id.* Recognizing the enormity of that market, Barrons called bapineuzumab "potentially 'the biggest drug of all time,'" and, before and during the Class Period, analysts characterized its prospects as the

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[8] The collaboration between Elan and Wyeth is governed by an agreement that generally provides that all material steps in their Alzheimer's Immunotherapy Program ("AIP") would be by agreement of both parties. *See* Memorandum of Law in Support of the Elan Defendants' Motion to Dismiss the Consolidated Complaint ("Def. Mem.") at 7-8.

[9] *See* Def. Mem. at 6; *see also* ¶3.

principal mover behind the price of Elan securities. ¶3. As the Associated Press observed, an effective treatment for Alzheimer's is one of the "holy grails of the pharmaceutical world," and the rewards to Elan for bringing a successful drug to market would be "incalculable." ¶85.

To win approval for bapineuzumab from the Food and Drug Administration ("FDA"), Elan planned to conduct both Phase 2 and Phase 3 clinical trials. ¶4. Phase 2 trials are designed to assess the dosing requirements, the efficacy at particular doses, and the safety of a drug on a medium-sized group of patients (roughly 30 to 300). *Id.*; *see also* ¶34. Phase 3 trials expand the safety and efficacy assessment to a larger group of patients (generally 300 to 2,000), often for a longer period of time. ¶4.

In April 2005, Defendants were to begin a Phase 2 clinical trial of bapineuzumab versus placebo involving 240 patients. ¶¶5, 32. Before commencing the Phase 2 trial, Elan and Wyeth agreed that they would conduct an "interim review" of the Phase 2 results before the study was complete to determine whether and how to proceed with Phase 3 studies. ¶¶5, 35, 37. Elan and Wyeth agreed that they would initiate Phase 3 studies before Phase 2 was completed if, and only if, the interim review showed that bapineuzumab was significantly outperforming placebo in Phase 2. ¶¶5, 36, 37. To assess bapineuzumab in the interim review, Elan and Wyeth agreed to use the two primary tests used in the study, the Alzheimer's Disease Assessment Scale-Cognitive Subscale ("ADAS-cog") and the Disability Assessment Scale for Dementia ("DAD"). ¶¶5, 34.

Defendants informed investors that for Elan and Wyeth to initiate Phase 3 studies before the Phase 2 clinical trial was complete, bapineuzumab would have to overcome the high hurdle of the interim review. ¶6. For example, Defendants stated that "Wyeth and ourselves have agreed to certain ***very specific criteria*** that need to be met in this Phase II trial in order to propel us into Phase III." ¶¶6, 37. Specifically, to "pass" the interim review, Elan and Wyeth agreed in advance that

bapineuzumab would have to outperform placebo on the strict, objective ADAS-cog and DAD tests. ¶43. Although the Companies declined to reveal those requirements publicly (*see* ¶37), they characterized them by saying the interim results of the Phase 2 clinical trial would have to be "***spectacular***," "***strong***," and "***very meaningful***." ¶¶6, 36, 37.

Defendants conducted the interim review of the Phase 2 results in May 2007. ¶7. The results did not satisfy the Companies' objective requirements for proceeding to Phase 3, meaning that bapineuzumab did not outperform placebo on either the ADAS-cog or DAD test, as the Companies had required. *Id.* As such, the results were far from spectacular, strong, or very meaningful. Further, higher doses of the drug were associated with vasogenic edema, a potentially dangerous accumulation of fluid in the brain, in patients that carried the Apolipoprotein E4 ("ApoE4") allele. *Id.* While not an original goal of the study, the results did indicate that a subset of patients, ApoE4 non-carriers, appeared to perform better on bapineuzumab than carriers of the allele. *Id.*

Despite having told investors that they would not proceed with Phase 3 studies before the Phase 2 clinical trial was complete unless bapineuzumab passed the strict criteria of the interim review, Defendants decided to proceed to Phase 3 trials even though the end-point criteria had not been satisfied. ¶8. Defendants' reasoning was simple: the massive investment in the research to date and potential windfall of an effective Alzheimer's drug, even if it worked only in a subset of the patient population, was significant enough to warrant the risk of proceeding to Phase 3 despite the negative Phase 2 interim review results. *Id.* Demonstrating their knowledge of both the poor overall efficacy of bapineuzumab and the safety issues associated with the drug, Defendants designed Phase 3 trials that separated ApoE4 carriers from non-carriers, and that did not use the high two-milligram dose of bapineuzumab that had been associated with vasogenic edema. *Id.*

Defendants failed to disclose these known and significant efficacy and safety issues to investors. On May 21, 2007, the first day of the Class Period, Defendants publicly announced that they were initiating Phase 3 trials, thus communicating to investors that bapineuzumab had met the objective criteria of the interim review with strong, very meaningful, and spectacular results. ¶¶9, 39. As a result, the price of Elan's ADRs jumped 12.5% in one day, to over $12. ¶¶9, 40. As one analyst, Davy Research, noted that same day: "No data have been disclosed, ***but both companies previously outlined that results from the Phase II interim analyses would need to be 'spectacular' to proceed***." ¶41.

Defendants' failure to disclose the negative results of the Phase 2 interim review had the important effect of helping to enroll the Phase 3 trials as quickly as possible. ¶10. These trials required over 4,000 Alzheimer's patients and their doctors to be willing to take a chance on an experimental drug, and the sooner they could be fully enrolled and completed, the sooner Defendants had a chance of burying the Phase 2 results and seeking FDA approval. ¶¶10, 88. Doctors are more likely to recommend and patients are much more likely to enroll in a study of a highly promising new drug than one that has previously shown mixed results. ¶¶10, 87. Although Defendants would eventually have to disclose the final results of the Phase 2 trial, they would not have to do so for at least a year, giving them plenty of time to enroll patients in the Phase 3 trials first. *Id.* Further, there was always the chance that the final results of the Phase 2 trial would be better than those observed at the interim review. *Id.*

Following the May 21, 2007 press release, Defendants continued to assert that the Phase 3 studies were proceeding based upon the results of the interim look at the Phase 2 data. ¶44. For example, during a July 26, 2007 conference call with analysts, defendant Ekman stated that: "The decision to move into Phase III was based on the totality of what the companies have learned from

our Alzheimer's immuno therapy programs, ***including the scheduled interim look at data from our ongoing Phase II study***. . . ." Such statements kept Elan securities trading at artificially inflated levels, above $17 per share. *Id.* At no time did Defendants disclose the results of the Phase 2 clinical trial they knew to be disappointing, or even suggest that those results were anything but "spectacular," "strong," and "very meaningful." *Id.*

When the Phase 2 trial was completed in April 2008, it confirmed that bapineuzumab failed to outperform placebo to a statistically significant degree on the ADAS-cog and DAD tests. ¶11. Further, the drug showed no dose response, meaning that higher doses of the drug did not correlate with greater improvement of symptoms. ¶¶11, 52. To the extent bapineuzumab outperformed placebo at all, it appeared to be because the non-carrier patients taking placebo got worse much faster than expected, thus making bapineuzumab's results look better. *Id.* And, in addition to the already known but undisclosed safety signal with vasogenic edema, there were a host of other potentially troubling side effects associated more strongly with bapineuzumab than placebo. *Id.*

Nonetheless, Defendants continued to make materially false and misleading statements concerning the Phase 2 trial and the decision to proceed to Phase 3. On May 1, 2008, defendant Martin made a presentation to investors at the Morgan Stanley 2008 Global Healthcare Unplugged Conference in Miami, Florida, during which he responded to investor questions regarding bapineuzumab. ¶46. Among other things, he stated:

> When we took an interim look, we clearly were looking for some specific things from a clinical point of view. There [were] a number of end points that we were looking at. We looked at it at a period of time that was still fairly early on in the Phase II. So we both – we looked for both specific points and specific trends in certain things and we put that together and we had discussions with both the European agency and the U.S. agency, the collective decision was we should move to a Phase III, simultaneously.
>
> We've kept the Phase II blinded because there is some chance, although again, as I've said to many people, it's not a high probability, but it is a probability. ***Or <u>some probability</u>, that the – if the Phase II data is <u>really spectacular</u> that there could be***

> ***some regulatory pathway to a filing that would be earlier than a full normal completion of Phase III***. That's going to depend, obviously on the data, its going to depend on discussions with the regulator etc.
>
> So what you should – what I believe that you should expect to see, what we would like you to see is that ***once you see the Phase II data, the marketplace and the investigators, the clinicians and everyone else who wants to look at it would say, geez, I understand exactly why Wyeth and Elan started a Phase III earlier than they did***.
>
> * * *
>
> I think it should be very obvious when we move to Phase III. So, without answering that specifically, I think it will be – ***it should be obvious why we moved to Phase III*** and I think that whether its statistical significance in all or parts, supported by trends, or trends with different combinations of data points. ***I think that the reason we moved to Phase III was we clearly saw enough data to move forward. It's a huge decision for us, and for Wyeth and its one that we don't take lightly***.
>
> So we are as anxious as anybody to look at the Phase II data, we've done a lot of work internally trying to predict what it would be. ***But our goal would be that as participants in the marketplace, that when you see the Phase II data, that there's unequivocal evidence why we moved to Phase III***. Whether it's statistical in everything, some things or combinations of statistical plus trends, ***our goal would be that it would be very clear to all of you sort of why we moved to Phase III***.

Id.

Defendants were loathe to admit the disappointing final results of the Phase 2 clinical trial for at least two reasons. ¶¶11-12. First, the Phase 3 studies were still enrolling, and any negative news about bapineuzumab would delay the Companies' completion of those studies and the possible approval of the drug and the revenues that would follow. ¶12. Second, Defendants did not want to admit to having misled the public, including investors, about the results of the interim review. Unfortunately for Defendants, however, investors were clamoring for the results of the study. *Id.*

Accordingly, Defendants scheduled a presentation for July 29, 2008 at the Alzheimer's Association's International Conference on Alzheimer's Disease 2008 ("ICAD") in Chicago, Illinois. ¶¶12, 14. Defendants elected, however, to announce the positive ApoE4 non-carrier results several weeks before the full study results were disclosed at ICAD. ¶12. This would give investors and the

public several weeks to consider the value of a potentially effective Alzheimer's drug for ApoE4 non-carriers, and would, Defendants hoped, blunt the effect of the negative Phase 2 results. *Id.*

Thus, on June 17, 2008, Defendants issued a press release announcing that patients in the Phase 2 clinical trial without the ApoE4 allele performed better on bapineuzumab than placebo to a statistically significant degree. ¶¶13, 50. The release acknowledged that patients with ApoE4 did not do so, but failed to disclose the magnitude of the miss, the absence of dose response, the unusually swift decline of the placebo patients, and the troubling safety results. ¶¶13, 50, 52. As a result, the price of Elan's ADRs jumped another 10% in one day. ¶¶13, 51.

On July 29, 2008, Elan and Wyeth presented the full results of the Phase 2 clinical trial at ICAD.[10] ¶¶14, 61. At that conference, and in a concomitant press release and conference call, investors learned for the first time that:

(a) The Phase 2 clinical trial established no dose response;

(b) Among the group in which some evidence of bapineuzumab's efficacy was purportedly found, the patients taking placebo showed a larger than expected cognitive decline. If the placebo group deteriorated more rapidly than average patients, this would exaggerate the efficacy results of bapineuzumab in the study;

(c) To manufacture bapineuzumab's statistically significant outperformance of placebo in the Phase 2 trial, Defendants changed the statistical model *post hoc* from linear to curvilinear. The original trial protocol called for linear modeling. Had Defendants not changed to a curvilinear model without informing investors, they could not have claimed that bapineuzumab outperformed placebo by a statistically significant margin, even in the ApoE4 non-carrier group;

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[10] As noted above, the SEC has issued a subpoena to Elan requesting records and information relating to this announcement. *See* Millkey Decl. Exhibit 1 at 2.

(d) Although the Phase 2 clinical trial showed bapineuzumab to outperform placebo in some patients over 18 months, there was no short-term advantage for bapineuzumab;

(e) Using the Mini Mental State Examination ("MMSE"), which Defendants characterized as a "key measure of cognitive function" (cognition being one of the four clinical endpoints of the trial (*see* ¶37)), there was no significant signal in the Phase 2 clinical trial that bapineuzumab worked better than the placebo;

(f) Nearly 10% of the Phase 2 participants (12 patients) taking bapineuzumab developed vasogenic edema versus zero patients in the placebo group (three of the patients so affected also developed bleeding in their brains);

(g) Three deaths were reported in the group taking bapineuzumab compared to none in the placebo group. One of the deaths was caused in part by an aortic dissection (a tear in the wall of this major artery), which has the potential to be related to drugs such as bapineuzumab;

(h) There were nine additional adverse effects that occurred two or more times as often in patients taking bapineuzumab versus placebo, and in more than 5% of such patients, including anxiety, vomiting, hypertension, paranoia, skin laceration, gait disturbance, and muscle spasms; and

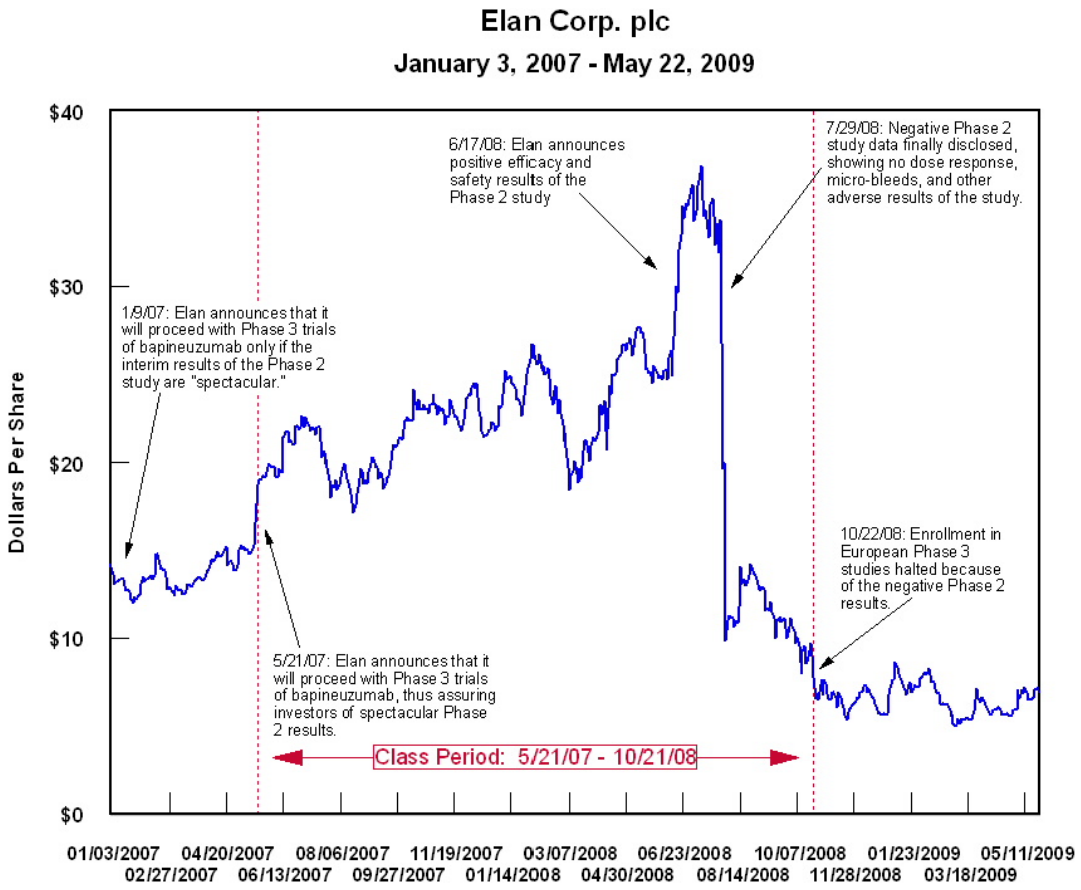
(i) Bapineuzumab not only failed to show a statistically significant benefit compared to placebo according to the original trial protocol, but failed to do so by a large margin. ¶¶14, 61-65.

When these facts were finally disclosed, the price of Elan's ADRs plunged 42% in one day, as the artificial inflation caused by Defendants' false and misleading statements came out of the price. ¶¶15, 66. Far from being "strong," "very meaningful," and "spectacular," and in compliance with the Companies' "very specific criteria," the adverse results of the Phase 2 trial were a material

setback for the developments of bapineuzumab. ¶15. They meant that, at a minimum, the Phase 3 trials would have to run their full 18-month courses before any FDA approval was possible, and that the drug would be targeted at only a subset of Alzheimer's patients. ¶¶15, 66. Even if bapineuzumab were eventually approved by the FDA, this delay of many months or even years (depending on how fast the Phase 3 studies enrolled) pushed any possible revenues further into the future and reduced their then-present value. *Id.* Finally, the previously undisclosed and negative Phase 2 data reduced the likelihood that bapineuzumab was greatly superior to Alzheimer's drugs already on the market, limiting its commercial potential. *Id.*

At the end of the Class Period, on October 22, 2008, Elan's partner in the development of bapineuzumab, Wyeth, disclosed in a conference call that European regulators had ordered that two Phase 3 studies of bapineuzumab be delayed in light of the adverse results of the Phase 2 trial. ¶¶16, 78. On this news, Elan's ADRs declined from $9.06 per share to $7.82 per share in one day, a decline of more than 13%, as the remaining artificial inflation came out of the price. ¶¶16, 79. All told, Elan's ADRs dropped $25.93 per share between July 29 and October 22, 2008, and investors suffered hundreds of millions of dollars in damages. ¶16.

The following chart presents the price of Elan's ADRs before, during, and after the Class Period:



¶17.

III. ARGUMENT

Defendants make two basic arguments in support of dismissal. First, they argue that Plaintiffs have not adequately alleged any materially false and misleading statements. Second, they argue that Plaintiffs have not adequately alleged scienter. For the reasons given below, both arguments fail.

A. Applicable Legal Standards

In ruling on a motion to dismiss, a court must "construe[] the complaint liberally, 'accepting all factual allegations in the complaint as true, and drawing all reasonable inferences in the plaintiff's favor.'" *In re Tower Auto. Sec. Litig.*, 483 F. Supp. 2d 327, 334 (S.D.N.Y. 2007). At issue on a 12(b)(6) motion "'is not whether a plaintiff is likely to prevail ultimately, but whether the claimant is entitled to offer evidence to support the claims.'" *Phelps v. Kapnolas*, 308 F.3d 180, 184-85 (2d Cir. 2002). The purpose of a pleading is to state a claim and provide adequate notice of that claim. In essence, "'[a] pleading is not a trial and plaintiffs are not required to marshal their evidence and sustain a verdict at this stage.'" *In re Nortel Networks Corp. Sec. Litig.*, 238 F. Supp. 2d 613, 621 (S.D.N.Y. 2003). Accordingly, a complaint "attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations," but rather must simply provide the grounds of entitlement to relief and raise a right to relief above the speculative level. *Bell Atl. Corp. v. Twombly* ("*Twombly*"), 550 U.S. 544, 555 (2007). Quoting *Twombly*, the United States Supreme Court held that to survive a motion to dismiss, a complaint must simply "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (quoting *Twombly*, 550 U.S. at 570). *Twombly* cautioned, however, that "[a]sking for plausible grounds . . . does not impose a probability requirement at the pleading stage"; it simply requires "enough fact[s] to raise a reasonable expectation that discovery will reveal evidence" to prove the claim. *Twombly*, 550 U.S. at 556. Under this standard, "[o]nly a statement of facts so conclusory that it fails to give notice of the basic events and circumstances on which a plaintiff relies should be rejected as legally insufficient under [Rule] 12(b)(6)." *Patane v. Clark*, 508 F.3d 106, 116 (2d Cir. 2007).

Securities fraud actions are subject to the pleading requirements of the Private Securities Litigation Reform Act of 1995 (the "PSLRA"), 15 U.S.C. §78u-4, *et seq.*, and Fed. R. Civ. P. 9(b),

which requires plaintiffs to identify "with particularity" the circumstances constituting the alleged fraud. Fed. R. Civ. P. 9(b). "To satisfy Rule 9(b), the complaint must '(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.'" *In re Regeneron Pharms., Inc. Sec. Litig.*, No. 03 Civ. 3111 (RWS), 2005 U.S. Dist. LEXIS 1350, at *34-35 (S.D.N.Y. Feb. 3, 2005) (quoting *Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1175 (2d Cir. 1993)).[11]

To state a claim for securities fraud under §10(b) of the Exchange Act, 15 U.S.C. §78j(b), and Rule 10b-5, a plaintiff must allege that the defendant: (1) made a misrepresentation or omission; (2) of material fact; (3) in connection with the purchase or sale of a security; (4) with scienter; (5) that the plaintiff relied upon; and (6) causing plaintiff to suffer damages. *See, e.g.*, *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 161 (2d Cir. 2000). As noted above, Defendants' challenges to the Complaint are limited to only the first and fourth of these elements.[12]

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[11] As the Second Circuit has confirmed, the PSLRA does not require the pleading of "all facts" or detailed evidentiary matters concerning an alleged fraud, but simply requires the Court to determine "whether the facts alleged are sufficient to support a reasonable belief" that defendants' statements were materially false or misleading. *Novak v. Kasaks*, 216 F.3d 300, 314 n.1 (2d Cir. 2000); *see also In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 72 (2d Cir. 2001) (even under Rule 9(b) and the PSLRA, "we do not require the pleading of detailed evidentiary matter in securities litigation").

[12] Although Defendants do not make a loss causation argument, they do suggest in passing that Elan's stock price remained depressed because of news relating to their MS drug, Tysabri. *See* Def. Mem. at 4-5, 23-24. It is undisputed, however, that upon the disclosure of the full Phase 2 results on July 29, 2008, the price of Elan's ADRs fell by $14.12 per ADR. *See* Millkey Decl. Exhibit 2. Moreover, even if Defendants had formally made this speculative argument, it would require expert testimony and could not be resolved on a motion to dismiss. *See, e.g.*, *In re Marsh & McLennan Cos., Inc. Sec. Litig.*, No. 04 Civ. 8144(CM), 2009 WL 5178546, at *17 (S.D.N.Y. Dec. 23, 2009) (multiple experts retained to address "complex damage and loss causation theories and analyses").

Accepting the Complaint's allegations as true and drawing all reasonable inferences in Plaintiffs' favor, the motion to dismiss should be denied.

B. The Complaint Adequately Alleges that Defendants Made False and Misleading Statements and Omissions of Material Fact

1. Defendants Misled Investors by Failing to Disclose Material Information in Elan's May 21, 2007 Press Release

On May 21, 2007, the first day of the Class Period, Elan and Wyeth issued a press release announcing their decision to initiate a Phase 3 clinical program for bapineuzumab. ¶39. The release stated that it was based, in part, on a "scheduled Interim look at data" from the ongoing Phase 2 study (*id.*), but did not give any further information about the results of that interim look. Nonetheless, investors had already received significant information about the Companies' prerequisites for moving to Phase 3 trials based upon their interim look at the Phase 2 data:

1. On October 5, 2006, Bob Ruffolo, a Senior Vice President of Wyeth and the President of Wyeth Research, had represented that the Companies "could advance directly into phase III in the first half of 2007" based on a future interim look at the Phase 2 data, "***but the results would have to be spectacular***." ¶36;

2. On January 9, 2007, defendant Martin had represented at JP Morgan's 25th Annual Healthcare Conference that the Phase 2 trial had four clinical endpoints (cognition, memory, quality of life, and imaging), that there would be an interim review of the Phase 2 data, and that "***Wyeth and ourselves have agreed to certain very specific criteria that need to be met in this Phase II trial in order to propel us into Phase III***." ¶37; and

3. At that same conference, defendant Ekman stated that Elan and Wyeth had decided not to provide the details of those "very specific criteria": "We have also jointly with Wyeth decided that we will not comment on when and how we're going to do the interim looks." *Id.* Nonetheless, he characterized those criteria by saying that, before moving to Phase 3, the interim data from Phase 2 would have to be "***strong***" and "***very meaningful***," and not be merely "***circumstantial***" – words that, with "spectacular," became proxies for the "very specific criteria" Elan and Wyeth had decided to use, but whose specifics they had decided not to disclose. *Id.*

Thus, any reasonable investor would have understood – and the stock price reaction shows they did understand – the Companies' May 21, 2007 announcement (that they were proceeding with Phase 3

clinical trials) to mean that the Phase 2 interim data were spectacular, strong, and very meaningful, and satisfied the Companies' "very specific," objective criteria. Indeed, that is precisely how securities analysts understood the announcement. *See, e.g.*, ¶40 (May 21, 2007 Davy Research analyst report stating that "No data have been disclosed, ***but both companies previously outlined that results from the Phase II interim analyses would need to be 'spectacular' to proceed.***"); ¶42 (July 31, 2007 Natixis Bleichroeder Inc. analyst report that "***We think the data at the interim look must have been profound*** and possibly involved a continual separation of drug from placebo over time – indicative of true disease modification.").

As the Complaint alleges, however, the Phase 2 data failed the objective standards of the interim review. Specifically, bapineuzumab failed to outperform placebo using the ADAS-cog and DAD tests in the interim review as required by Elan and Wyeth's prior agreement. ¶43. Further, vasogenic edema was associated with high doses of bapineuzumab in ApoE4 carriers. *Id.*

Defendants' failure to disclose the truth about the results of the interim look violated the federal securities laws. Although Defendants did not affirmatively misrepresent those results in the May 21, 2007 announcement (that Elan and Wyeth were moving to Phase 3), the press release was misleading in light of their ***earlier*** statements that they would proceed to Phase 3 only in highly specific circumstances – *i.e.*, only if the Phase 2 interim look revealed data that were "spectacular," "strong," and "very meaningful," and if that data satisfied the specific, objective criteria Elan and Wyeth had agreed upon. Because Defendants moved to Phase 3 testing without satisfying the objective criteria of the interim review, and without disclosing that fact, they misled investors.

On the element of falsity, therefore, this case is very similar to *In re Geopharma, Inc. Securities Litigation*, 399 F. Supp. 2d 432 (S.D.N.Y. 2005). In early to mid-2004, before the class period, Geopharma announced that it was developing a drug for the treatment of a condition called

mucositis. *Id.* at 436-37. By September 2004, however, Geopharma realized that the product it was developing, Mucotrol, was actually a medical "device" rather than a "drug" – a distinction with important consequences. *See id.* at 437 (explaining distinction). Nonetheless, after Geopharma received marketing approval for Mucotrol from the FDA on November 24, 2004, Geopharma issued a press release announcing that it had received FDA approval for Mucotrol, which it described as a "prescription product," causing Geopharma's stock price to shoot up. *Id.* After the truth was revealed – that Mucotrol was a medical device rather than a drug – the stock price fell and investors sued. *Id.* at 439 (ultimately dismissed on other grounds).

In seeking dismissal, defendants argued that their press release was literally true because Mucotrol was, in fact, a "prescription product." *Id.* at 446. In effect, the defendants were blaming plaintiffs for ***assuming*** Mucotrol was a drug. Citing the defendants' earlier description of Mucotrol as a drug, however, the court disagreed:

> [A] reasonable investor could have been misled by failing to absorb the fine distinction between the terms "drug" and "prescription product." Therefore, plaintiffs have properly alleged that the use of a rather vague term such as "prescription product" in the December 1 Release, ***given the context of GeoPharma's previous statements***, could be objectively misleading.

Id. at 447 (footnote omitted; citing *In re Ribozyme Pharm., Inc. Sec. Litig.*, 119 F. Supp. 2d 1156, 1162 (D. Colo. 2000) (allegation that press release was false and misleading in the context of earlier press release was sufficient under Fed. R. Civ. P. 9(b) and the PSLRA)). In other words, although the term "prescription product" in the press release was literally true, the release was nonetheless misleading because of Geopharma's ***earlier*** announcement that it was developing a drug (as opposed to a device). *See also McMahan & Co. v. Wherehouse Entm't, Inc.*, 900 F.2d 576, 579 (2d Cir. 1990) ("Some statements, although literally accurate, can become, through their context and manner of presentation, devices which mislead investors. For that reason, the disclosure required by the

securities laws is measured not by literal truth, but by the ability of the material to accurately inform rather than mislead prospective buyers.").

Just so here, the May 21, 2007 press release was false and misleading in the context of Defendants' earlier statements specifying the circumstances in which they would proceed to Phase 3 clinical trials – that is, only if the Phase 2 interim data were "spectacular," "strong," and "very meaningful," and when they met the specific, objective criteria on which Wyeth and Elan had agreed. Given these earlier representations, and in the absence of any contrary language in the May 21, 2007 press release, reasonable investors understood the results of the interim look into the Phase 2 data to be far more favorable than they actually were. Investors were, therefore, misled in violation of the federal securities laws. *See, e.g.*, *In re Time Warner, Inc. Sec. Litig.*, 9 F.3d 259, 268 (2d Cir. 1993) ("[a] duty to disclose arises whenever secret information renders prior public statements materially misleading"); *In re Flag Telecom Holdings, Ltd. Sec. Litig.*, 618 F. Supp. 2d 311, 323 (S.D.N.Y. 2009) (denying summary judgment motion and holding: "'[t]he touchstone of the inquiry is not whether isolated statements within a document were true, but whether defendants' representations or omission . . . [would] mislead a reasonable investor'") (quoting *Halperin v. eBanker USA.com*, 295 F.3d 352, 357 (2d Cir. 2002)).

2. None of Defendants' Arguments Relating to the May 21, 2007 Press Release Is Meritorious

Defendants make three arguments in support of their position that there were no false or misleading statements in the May 21, 2007 press release. None is meritorious.

a. Plaintiffs Have Adequately Alleged that the Results of the Interim Phase 2 Review Were Not Strong, Very Meaningful, or Spectacular

Although the Complaint clearly alleges that the interim results of the study failed the objective criteria of the interim review and, thus, were neither "strong," "very meaningful," nor

"spectacular," *see, e.g.*, ¶¶7, 43, Defendants contend that Plaintiffs have made these allegations "without alleging facts that explain how or why." Def. Mem. at 29. Moreover, Defendants argue that the interim data actually satisfied these criteria – that a "positive effect" in slowing the rate of decline in a subgroup of persons who have Alzheimer's (those who did not carry the ApoE4 allele) "could fairly be described as strong, meaningful, or spectacular," and therefore in compliance with the "very specific criteria" Elan and Wyeth had agreed upon for the interim look. *Id.* Defendants are incorrect.

First, the Complaint alleges specific reasons why the interim data failed the objective criteria of the review and were, thus, neither strong, very meaningful, nor spectacular. It alleges that Elan and Wyeth agreed to assess the interim data against the two primary tests used in the study, the ADAS-cog and DAD tests discussed above (*see also* ¶¶5, 34, 43, 47), that bapineuzumab did not outperform placebo as required using either test (*see* ¶¶7, 43), and that higher doses of the drug were associated with vasogenic edema, a potentially dangerous accumulation of fluid in the brain, in patients that carried the ApoE4 allele. *See id.* These allegations flatly contradict Defendants' claim that Plaintiffs fail to explain how the interim data were not strong, very meaningful, or spectacular. Moreover, as Plaintiffs allege, these facts were readily known to Defendants, as evidenced by the dosing, patient and endpoint modifications Defendants made to the Phase 3 study. *See, e.g.*, ¶¶8, 61.

Second, Defendants contend that Plaintiffs give insufficient detail about "the standard Elan and Wyeth intended to use in the interim review in order to determine whether to proceed to Phase III." Def. Mem. at 29. Defendants are wrong. As noted, the Complaint alleges that Elan and Wyeth "agreed to use the two primary tests used in the study," the ADAS-cog and the DAD, "to assess

bapineuzumab in the interim review." ¶5. And Plaintiffs specifically pleaded that, at the interim review, bapineuzumab did ***not*** meet that objective standard. ¶43.[13]

Third, whether bapineuzumab showed some "positive effect" among a subgroup of the test population identified after the fact is irrelevant to whether the May 21, 2007 press release was false and misleading. Before the interim look, Defendants represented that Elan and Wyeth had agreed to apply "very specific," objective criteria in determining whether to advance to Phase 3 clinical trials. ¶37. The only relevant question is, therefore, did the data satisfy those objective, pre-determined criteria – ***not*** whether Elan could find some silver lining in the test results for a sub-group of subjects after the fact. The Complaint alleges that the data failed the objective tests that Elan and Wyeth had agreed upon (*see* ¶¶7, 43) – an allegation Defendants have not denied. While Defendants may have at the time, and particularly have now, shifted the "standard" they used in reviewing the Phase 2 interim results, Plaintiffs allege (and there is no real dispute) that the results did ***not*** demonstrate efficacy under the two primary tests used in the study. ¶¶43, 52, 65.

Furthermore, to the extent Defendants are really arguing that the May 21, 2007 press release was neither false nor misleading because the interim look actually satisfied the objective criteria (which it did not), that argument would present an issue of fact that is inappropriate for resolution on

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[13] Even if Plaintiffs had not so alleged – which they did – they are not, at this early stage of the litigation (before discovery), required to plead evidence or facts – particularly evidence or facts that are within Defendants' exclusive possession, such as information about the specific requirements of the interim look. *See, e.g.*, *In re Bausch & Lomb, Inc. Sec. Litig.*, No. 01-CV-6190-CJS, 2003 WL 23101782, at *26 (W.D.N.Y. Mar. 28, 2003) (securities plaintiffs "are not required to plead evidence"); *In re Sterling Foster & Co., Inc., Sec. Litig.*, 222 F. Supp. 2d 216 (E.D.N.Y. 2002) (holding that "'a complainant is not required to plead evidence,'" and is not required to plead facts that are "'within the exclusive provenance of [others]'") (quoting, respectively, *Schlick v. Penn-Dixie Cement Corp.*, 507 F.2d 374, 379 (2d Cir. 1974), and *Segal v. Gordon*, 467 F.2d 602, 608 (2d Cir. 1972)). Here, as alleged in the Complaint, Defendants announced that they would not disclose the precise methodology for the interim looks. *See* ¶37 ("We have also jointly with Wyeth decided that we will not comment on when and how we're going to do the interim looks.") (quoting Ekman).

a motion to dismiss.[14] *See, e.g.*, *Dougherty v. Town of North Hempstead Bd. of Zoning Appeals*, 282 F.3d 83, 92 (2d Cir. 2002) ("We believe these are issues of fact that cannot properly be determined on a motion to dismiss."); *Scholastic*, 252 F.3d at 74 ("It may be that at summary judgment, or even at trial, the defendants [may] demonstrate [such facts] that a reasonable jury could not find that they violated the securities laws. But any speculation to that effect is inappropriate at the pleadings stage."); *Oladokun v. Ryan*, No. 06 Civ. 2330(KMW), 2009 WL 857460, at *5 (S.D.N.Y. Mar. 31, 2009) (issues of fact may not be resolved on a motion to dismiss); *Tower Auto.*, 483 F. Supp. 2d at 334 (courts must accept all factual allegations in complaint as true); *In re OSI Pharms., Inc. Sec. Litig.*, No. 2:04-CV-5505 (JS) (WDW), slip op. at 21 (E.D.N.Y. Mar. 31, 2007) ("the veracity of the statements is a disputed issue of fact that may not be appropriately decided in favor of Defendants at this stage of the proceedings").[15]

In *OSI*, for example, the defendant company developed a cancer drug called Tarceva. Although OSI had represented that Tarceva would "increase the overall survival of lung cancer patients" (slip op. at 4), the plaintiffs alleged that Tarceva was not as effective as OSI claimed in two subgroups of patients tested in a clinical study. *Id.* at 5. On their motion to dismiss, the defendants' principal argument was that "the alleged statements or omissions were either true or not misleading." *Id.* at 21. The court rejected that argument, holding that, on a motion to dismiss, the court could not

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[14] If Defendants are suggesting that the interim data satisfied the Companies' "very specific criteria" even though the final data did not, that is very unlikely as a factual matter. As the Complaint alleges, "Although the Phase 2 Study showed bapineuzumab to outperform placebo in some patients over 18 months, there was ***no short-term advantage for bapineuzumab***." ¶14(d). Thus, any data showing a positive effect of the drug were more likely to be evident at the end of the study, rather than earlier, upon the interim look.

[15] *OSI Pharms.* is submitted in Plaintiffs' Compendium of Unreported Authorities in Support of Their Motion to Strike, and in Opposition to Defendants' Motion to Dismiss, dated February 16, 2010.

determine "the veracity of the statements in question," as that defense presented a "disputed issue of fact" inappropriate for resolution at that stage of the litigation. *Id.*

b. Nothing in the May 21, 2007 Announcement Negated or Extinguished Defendants' Earlier Representations Concerning Their Interim Look at the Phase 2 Data

Defendants argue that the May 21, 2007 press release extinguished their earlier representations concerning the interim look into the Phase 2 data by setting forth reasons ***in addition to*** the interim look in support of moving to Phase 3. *See* Def. Mem. at 30-31. Defendants are referring to the following language in the press release:

> This decision was based on the seriousness of the disease and the totality of what the companies have learned from their immunotherapy programs, ***including a scheduled Interim look at data from an ongoing Phase 2 study***, which remains blinded. No conclusion about the Phase 2 study can be drawn until the study is completed and the final data are analyzed and released in 2008.

¶39; *see also* Def. Mem. at 30, 31 ("Under these circumstances, the earlier statements could not have remained alive in the mind of a reasonable investor."). Had the May 21, 2007 press release ***omitted*** the interim look as a reason for going forward, Defendants might have a point, but it does not; it simply lists two additional reasons – the seriousness of the disease (which is a given) and, vaguely, the totality of the Companies' learning. Reasonable investors would continue to understand the Companies' earlier requirements for the interim look – that the data meet the "very specific," objective criteria agreed upon by the Companies, and thus be "strong," "very meaningful," and "spectacular" – were still in effect. Indeed, the import of Defendants' May 21, 2007 announcement and investor reaction would have been radically different if they had revealed that they were

proceeding with Phase 3 trials because of the seriousness of the disease and the totality of what they had learned alone, ***despite*** the poor results of the Phase 2 interim review.[16]

Nor does the last sentence of the quoted passage – that no conclusion about the Phase 2 study should be drawn until the study is complete – negate Defendants' earlier statements. That is merely stating the obvious: that an interim look is only that, an interim look from which final and definitive conclusions cannot be drawn. That did not, however, give Defendants a license to lie about the interim results.

Completely undermining Defendants' argument that "the earlier statements could not have remained alive in the mind of a reasonable investor" is the exchange defendant Martin had with an unidentified audience member at the May 1, 2008 Morgan Stanley 2008 Global Healthcare Unplugged Conference in Miami, Florida – one year ***after*** the issuance of the May 21, 2007 press release. *See* ¶46. During the conference, the audience member asked:

> You guys have talked about in the past that you would go into Phase III, only really on the basis of really clinically meaningful and even ***spectacular*** data and you've also indicated possibly being able to file sub par E on the Phase IIB data, the final data. I guess I'm trying to understand, what does that mean? Those qualitative descriptions. Does that mean we should expect statistical significance on Phase II? Does that mean we should expect trends? What exactly is ***spectacular***?

¶46. Far from enlightening the audience member that the results of the Phase 2 interim look had not been spectacular, very meaningful, and strong, Martin continued to convey the clear impression that the results were far better than they in fact were. *See id.* ("So, without answering that specifically, I think it will be – ***it should be obvious why we moved to Phase III*** and I think that whether its statistical significance in all or parts, supported by trends, or trends with different combinations of

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[16] To wit, neither the seriousness of the disease nor the totality of what Defendants had learned changed on July 28, 2008 when Defendants disclosed the true facts about the Phase 2 study. Yet, in response, Elan's ADR price dropped 42%. *See* ¶¶15, 66.

data points. ***I think that the reason we moved to Phase III was we clearly saw enough data to move forward. It's a huge decision for us, and for Wyeth and its one that we don't take lightly***.").

Thus, the May 21, 2007 press release did nothing to erase Defendants' earlier representations concerning the prerequisites for moving to Phase 3 clinical trials.

c. Defendants' Representations Were Neither Expressions of Opinion Nor Puffery

Defendants argue that, even if they did decide to move to Phase 3 testing based upon interim data that failed to satisfy the "very specific," objective criteria they had agreed upon with Wyeth, they had no obligation to update investors concerning their changed intentions. Def. Mem. at 31. Defendants contend that, "Because the statements were expressions of opinion, they were not sufficiently concrete to require updating." *Id*. at 32. Defendants also argue that their earlier representations were soft, non-actionable puffery (*id.* at 32-33), a defense whose acceptance by the courts has been "increasingly rare."[17] These arguments mischaracterize both the claims Plaintiffs are asserting and the statements at issue in this lawsuit.

First, this is not a case, like those on which Defendants rely (*see* Def. Mem. at 32), in which the defendant expressed a hope, intention, or opinion about the ***future*** that simply did not pan out. *See, e.g., In re International Business Machines Corporate Sec. Litig.* ("*IBM*"), 163 F.3d 102, 109-10 (2d Cir. 1998) (expressing intention not to cut dividend, but later cutting it); *Time Warner*, 9 F.3d at 267 (expressing intention to finance debt through strategic partnerships, but later issuing securities instead); *see also* Def. Mem. at 32. Defendants are correct that, in circumstances such as those, there

[17] *In re Cardinal Health Inc. Sec. Litig.*, 426 F. Supp. 2d 688, 749 n.70 (S.D. Ohio 2006) (citing *Brumbaugh v. Wave Sys. Corp.*, 416 F. Supp. 2d 239, 250 n.11 (D. Mass. 2006)).

is no duty to update. *See, e.g.*, *IBM*, 163 F.3d at 110 ("there is no duty to update vague statements of optimism or expressions of opinion").

This case, however, is different. Defendants did not express a hope, intention, or opinion about the Companies' ability to move to Phase 3 testing, but then were unable to do so. Rather, Defendants represented that they would move to Phase 3 ***only if the "very specific criteria" were satisfied*** upon an interim look at the Phase 2 data. They later ***did*** proceed to Phase 3 testing after an interim look, but did so even though the interim review showed that bapineuzumab did ***not*** outperform placebo on either the ADAS-cog or DAD test. Because Defendants failed to disclose that they moved to Phase 3 without meeting those criteria, investors were misled into believing that the criteria were satisfied, and that the interim data were far more favorable than they actually were. There is no question that, in these circumstances, Defendants are guilty of an actionable omission – even under the Second Circuit case law that Defendants themselves cite. *See Time Warner*, 9 F.3d at 268 ("one circumstance creating a duty to disclose arises when disclosure is necessary to make prior statements not misleading"); *IBM*, 163 F.3d at 110 ("A duty to update may exist when a statement, reasonable at the time it is made, becomes misleading because of a subsequent event."). *See also Geopharma*, 399 F. Supp. 2d at 447 (court found a statement that was literally true to be false and misleading because defendants' earlier representations caused plaintiffs to misunderstand it).

Second, Defendants cannot fairly or accurately characterize the representations in this case as "insufficiently concrete," "soft," or "puffery." In discussing the Companies' prerequisites for moving to Phase 3 testing based upon the interim look, defendant Martin repeatedly underscored that Elan and Wyeth had agreed to "very specific criteria" for evaluating the interim-look data:

> And then, lastly, ***the important thing to emphasize is that Wyeth and ourselves have agreed to certain very specific criteria that need to be met in this Phase II trial in order to propel us into Phase III***.

* * *

> What we've given the independent review group is ***very specific criteria*** that we're looking for. And we came up with that criteria by looking at a vast array of data, some of which I went through a little while ago that lets us anticipate which of these endpoints are going to move when and to what amplitude.

¶37. Because Elan and Wyeth had determined not to reveal to the market precisely what those "very specific criteria" were (*see id.*),[18] defendant Ekman characterized them generally by saying the results of the interim look would have to be "strong" and "very meaningful" (*id.*), or, as Bob Ruffolo of Wyeth had previously said, "spectacular." ¶36. Thus, the terms "strong," "very meaningful," and "spectacular" were, in effect, proxies for the "very specific criteria" Defendants had discussed but declined to describe. *See, e.g., In re Viropharma, Inc. Sec. Litig.*, No. CIV. A. 02-1627, 2003 WL 1824914, at *6 (E.D. Pa. Apr. 7, 2003) ("To determine whether a statement is puffery, a court must examine the context in which the statement was made."). But "the important thing to emphasize" was the specificity of the criteria required before moving to Phase 3: the Companies would do so only if bapineuzumab met the objective criteria of the ADAS-cog and DAD tests, and not with mere "circumstantial evidence of efficacy." ¶37. Thus, in context, Defendants' statements and omissions cannot be dismissed as "soft" or mere "puffery."

For the same reason, Defendants cannot properly characterize any of the statements at issue as "opinion." At the January 9, 2007 conference, which occurred months before the interim look, the Companies were not expressing an opinion that the data were likely to be strong, very meaningful, or spectacular (in compliance with the criteria the Companies had agreed upon). Rather, they were merely stating, as a factual matter, the circumstances in which they would move to Phase 3 trials, a critical step in the process of getting a drug approved by the FDA. They would do so only

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[18] As defendant Ekman stated: "We have also jointly with Wyeth decided that we will not comment on when and how we're going to do the interim looks." ¶37.

if the interim data proved to be "strong," "very meaningful," and "spectacular" – not in some intangible sense, but in the sense of satisfying the "very specific criteria" that Elan and Wyeth had agreed upon at the outset of the trial. Thus, when Defendants announced that they were proceeding to Phase 3, the market understood that the interim data had proven to be "spectacular," "strong," and "very meaningful" according to Defendants' specific, objective criteria. For the reasons explained in the Complaint (and above), that was not true. *See, e.g.*, *Billhofer v. Flamel Techs., SA*, No. 1:07-cv-99920 (CSH), 2009 WL 3241399, at *7 (S.D.N.Y. Oct. 5, 2009) (representation that program was a "success" and that interest in the technologies "has never been higher" was not mere puffery).

In every case that Defendants cite, the defendants used truly "soft" words expressing mere corporate optimism, not (as here) terms linked with "very specific criteria" for establishing a future course of conduct. *See Elliot Assocs., L.P., v. Covance, Inc.*, No. 00 Civ. 4115 SAS, 2000 WL 1752848, at *10 (S.D.N.Y. Nov. 28, 2000) (merger discussions were "on track"); *In re Bristol-Meyers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 557 (S.D.N.Y. 2004) (drug had "blockbuster potential"); *Noble Asset Mgmt. v. Allos Therapeutics, Inc.*, No. CIVA-04CV-1030-RPM, 2005 WL 4161977, at *11 (D. Colo. Oct. 20, 2005) (describing clinical trial results as "strong," "compelling," "impressive," and "positive").[19]

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[19] The same is true of each of the non-pharmaceutical cases that Defendants cite (*see* Def. Mem. at 33): each of them uses the soft language of corporate puffery and opinion to describe results or expected future results. None of them concerns the "specific criteria" that must be satisfied before pursuing a particular course of conduct. *See San Leandro Emergency Medical Group Profit Sharing Plan v. Philip Morris Cos.*, 75 F.3d 801, 806-07, 811 (2d Cir. 1996); *In re Xinhua Fin. Media, Ltd. Sec. Litig.*, Master File No. 07 Civ. 3994(LTS)(AJP), 2009 WL 464934, at *8 (S.D.N.Y. Feb. 25, 2009); *Pollio v. MF Global, Ltd.*, 608 F. Supp. 2d 564, 571 (S.D.N.Y. 2009); *Lasker v. N.Y. State Elec. & Gas Corp.*, 85 F.3d 55, 58-59 (2d Cir. 1996).

3. Defendant Martin Misled Investors by Continuing to Withhold Material Information About the Interim Look at the May 1, 2008 Morgan Stanley Conference

On May 1, 2008, defendant Martin made a presentation at the Morgan Stanley 2008 Global Healthcare Unplugged Conference in Miami, Florida. *See* ¶46. During the conference, Martin received a question from an unidentified audience member about Bob Ruffolo's October 5, 2006 representation that the results of the interim look would have to be "spectacular" for the Companies to move directly into Phase 3 testing in the first half of 2007. *See* ¶36. The audience member asked:

> You guys have talked about in the past that you would go into Phase III, only really on the basis of really clinically meaningful and even spectacular data and you've also indicated possibly being able to file sub par E on the Phase IIB data, the final data. I guess I'm trying to understand, what does that mean? Those qualitative descriptions. Does that mean we should expect statistical significance on Phase II? Does that mean we should expect trends? What exactly is spectacular?

¶46.

Rather than correct the misunderstanding that Defendants had created with their May 21, 2007 announcement that the Companies were proceeding to Phase 3 testing – that the interim-look data satisfied the "very specific criteria" the Companies had agreed upon, and were "strong," "very meaningful," and "spectacular" – defendant Martin perpetuated the misunderstanding. Using the blinded nature of the Phase 2 study as an excuse to avoid giving specific information about the interim look (*see* ¶46), Martin responded as follows, *inter alia*, even going so far as to continue to use the word "spectacular":

> We've kept the Phase II blinded because there is some chance, although again, as I've said to many people, it's not a high probability, but it is a probability. Or ***some probability***, that the – ***if the Phase II data is really spectacular that there could be some regulatory pathway to a filing that would be earlier than a full normal completion of Phase III***. That's going to depend, obviously on the data, its going to depend on discussions with the regulator etc.
>
> So what you should – what I believe that you should expect to see, what we would like you to see is that ***once you see the Phase II data, the marketplace and the investigators, the clinicians and everyone else who wants to look at it would say,***

> ***geez, I understand exactly why Wyeth and Elan started a Phase III earlier than they did***.

¶46.

> Either this same or another audience member also asked:
>
> So, just to be clear on the question of whether we should expect significance or not, understanding that this is a relatively small study and particularly at the interim it was even smaller data set you had to look at. Would we expect significance in any one dose, would we expect significance in all three of the doses that you eventually took into Phase III. Would we expect significance on maybe a combined analysis of those three dosing cohorts or should we just not expect any kind of statistical significance and just pay attention to trends. How would we look at – how would you want us to look at it?

Id. Martin again responded in such a way as to reinforce the perception of spectacular Phase 2 result and mislead investors:

> I think it should be very obvious when we move to Phase III. So, without answering that specifically, I think it will be – ***it should be obvious why we moved to Phase III*** and I think that whether its statistical significance in all or parts, supported by trends, or trends with different combinations of data points. ***I think that the reason we moved to Phase III was we clearly saw enough data to move forward. It's a huge decision for us, and for Wyeth and it's one that we don't take lightly***.

¶46.

These remarks – that there was "some probability" of "spectacular" final Phase 2 data, that people would say "geez, I understand exactly why Wyeth and Elan started a Phase III earlier than they [would have in the ordinary course]," that "it should be obvious why we moved to Phase III," that "the reason we moved to Phase III was we clearly saw enough data to move forward," and that "It's a huge decision for us, and for Wyeth and it's one that we don't take lightly" – would do nothing to dispel investors' misimpression of the results of the Phase 2 interim look. In the context of Defendants' earlier representations – that they would move to Phase 3 only if the interim-look data were "strong," "very meaningful," and "spectacular," and satisfied the Companies "very specific criteria" for moving forward – these remarks only compounded Defendants' deception.

In their Argument, Defendants barely even address Martin's May 1, 2008 remarks. In a section concerning an altogether different statement – the May 21, 2007 press release (issued almost a year before the Morgan Stanley conference) – Defendants argue, almost as an aside, that Martin made no actionable statements at the Morgan Stanley conference: "Similarly, Mr. Martin's comments at the May 1, 2008 conference, while noting the previous statements that Elan and Wyeth wanted to see 'clinically meaningful' data from the interim review, made clear that this did not necessarily mean statistical significance." Def. Mem. at 31. This argument, that Martin's comments were in fact "correct" (*see id.*) – that is, truthful and not misleading – should fail for at least two reasons.

First, whether a reasonable investor would be misled by the statements in question presents an issue of fact not amenable to resolution on a motion to dismiss. For this reason alone, the Court should reject Defendants' argument. *See, e.g.*, *Geopharma*, 399 F. Supp. 2d at 441 ("a statement or omission is actionably misleading when a reasonable investor would have been misled. This determination is fact-specific, rarely amendable to disposition as a matter of law") (footnotes omitted; citing, *inter alia*, *Wertheim Schroder & Co. v. Avon Prods., Inc.*, No. 91 Civ. 2287, 1993 WL 126427, at *15 (S.D.N.Y. Apr. 1, 1993)); *see also McMahan*, 900 F.2d at 579, 582 (finding triable issues of fact whether defendants' representations would have mislead a reasonable investor).

Second, Defendants mischaracterize what Martin actually said. He did ***not*** say, as Defendants represent, that "clinically meaningful" data "did not necessarily mean statistical significance." Def. Mem. at 31. To the contrary, Martin pointedly left open a possibility he knew to be untrue – that ***all*** the interim-look data were statistically significant. This is what he actually said:

> [I]t should be obvious why we moved to Phase III and I think that ***whether its statistical significance in all or parts***, supported by trends, or trends with different combinations of data points.

* * *

> ***Whether it's statistical in everything, some things or combinations of statistical plus trends***, our goal would be that it would be very clear to all of you sort of why we moved to Phase III.

¶46. But Defendants knew that the interim results failed the objective ADAS-cog and DAD tests ***and***, by this time, Defendants also knew that, for the overall patient population, the bapineuzumab results were ***not*** statistically significantly better than placebo.

4. None of Defendants' Arguments Relating to the June 17, 2008 Press Release Is Meritorious

Although Defendants devote more than eight pages of their memorandum to disputing that the statements contained in the Companies' June 17, 2008 press release (*see* Def. Mem. at 35-44), they summarize their entire argument in their Preliminary Statement: "Everything stated in the June 17, 2008 press release was absolutely true, and plaintiffs cannot allege otherwise." *Id.* at 4. Defendants' argument fails for numerous reasons.

Whether the statements in the June 17, 2008 release were true or not is not the question the federal securities laws address. Rather, they ask whether those statements would mislead a reasonable investor, regardless of whether they are technically true. *See Flag Telecom*, 618 F. Supp. 2d at 323 (denying summary judgment motion and holding: "'[t]he touchstone of the inquiry is not whether isolated statements within a document were true, but whether defendants' representations or omission . . . [would] mislead a reasonable investor'") (quoting *Halperin v. eBanker USA.com*, 295 F.3d 352, 357 (2d Cir. 2002)); *see also Time Warner*, 9 F.3d at 268 ("[a] duty to disclose arises whenever secret information renders prior public statements materially misleading").

Given the known, negative results of the Phase 2 trial as of June 2008, Plaintiffs allege that Defendants' incomplete disclosure of Phase 2 results on June 17, 2008 was misleading. Defendants elected to speak when they did not have to, obligating them to disclose all material facts about the bapineuzumab results. Nevertheless, Defendants failed to disclose critical, negative results,

including the absence of dose response, the abnormal deterioration of the placebo group, Defendants' *post hoc* change of the statistical model from linear to curvilinear, and the other items listed in paragraph 52 of the Complaint. Whether or not some of the positive results Defendants chose to disclose were accurate is irrelevant, because Defendants withheld and continued to withhold the material, negative results of the study.

One need only compare the reaction of Elan's ADR price on June 17, 2008, when Defendants' self-selected and so-called "top-line" results were announced, with the reaction on July 29, 2008, when the full Phase 2 results were announced, to see that investors continued to be misled on June 17, 2008. On June 16, 2008, the day before the announcement, Elan's ADRs closed at $27.11 per ADR, on volume of 3,130,344 ADRs. Millkey Decl. Exhibit 2. On June 17, 2008, after Defendants announced the positive results of the study, Elan's ADRs closed up at $30 per ADR, on volume of 30,479,114 ADRs – almost 10 times the volume of the previous day. *See id.*; ¶13; As the market's reaction makes clear, investors understood Defendants' self-selected results to be conveying ***favorable*** news. Indeed, Elan's stock price continued to rise, closing as high as $36.82 per ADR on July 10, 2008. *See* ¶16. By contrast, after the full Phase 2 results – including the previously concealed negative results – were communicated on July 29, 2008, the reaction was very different. The following day – July 30, 2008 – the price of Elan's ADRs fell $14.12 per ADR to close at $19.63 (down 42% from the prior day's close of $33.75), on volume of 82,162,857 ADRs. *See* Millkey Decl. Exhibit 2.

Similarly, the reaction of industry analysts to the June 17 and July 29, 2008 announcements was very different, making it clear that the market was misled by the June 17 announcement. On June 17, Credit Suisse published a post-announcement analyst report entitled "Key Alzheimer's data read encouraging" (¶53), and Natixis Bleichroeder published an analyst report entitled "ELN: No

Negative Babby Data Keeps Us Happy." ¶54. The following day, Davy Research published an analyst report entitled "Bapineuzumab provides better-than-expected subset data: risked valuation upgraded to $31" (¶55), and on July 8 Cowen and Company published an analyst report stating that "Bapineuzumab Phase II Results Exceeded Expectations." ¶56; *see also* ¶¶57-60. By contrast, after Defendants' July 29, 2008 revelation of the full Phase 2 results, Adam Feuerstein published an article on *TheStreet.com* entitled "Elan-Wyeth Alzheimer's Data Spook Bulls," which stated, *inter alia*: "what we saw from the bapineuzumab study just looked like so much randomness." ¶67. The next day, Caris & Company published an analyst report that stated, in part: "[E]nough information was revealed to suggest that the Phase II results could be completely invalid." ¶68. Also on July 29, Cowen and Company published a report stating that "The presentation of the detailed bapineuzumab Phase II data yesterday at the ICAD meetings raised unexpected questions about the robustness of bapineuzumab's apparent efficacy – and about the chances for success in Phase III." ¶69; *see also* ¶¶70-76.

The positive reaction to the publication of Defendants' flattering version of the study results, and the opposite, negative reaction to the full results, demonstrates that the market was misled. Thus, the Court cannot rule, as a matter of law, that the Companies' June 17, 2008 press release was not misleading. *See Geopharma*, 399 F. Supp. 2d at 441 ("a statement or omission is actionably misleading when a reasonable investor would have been misled. This determination is fact-specific, rarely amendable to disposition as a matter of law") (footnotes omitted; citing, *inter alia*, *Wertheim Schroder*, 1993 WL 126427, at *15); *see also McMahan*, 900 F.2d at 579, 582 (finding triable issues of fact about whether defendants' representations would have mislead a reasonable investor).

This case is different, therefore, from the ones on which Defendants rely. *See* Def. Mem. at 35. In *In re Adolor Corp. Sec. Litig.*, 616 F. Supp. 2d 551 (E.D. Pa. 2009), for example, the court

specifically found that there was no inaccurate, incomplete or misleading prior disclosure requiring a corrective statement. *Id.* at 569 ("Plaintiffs do not allege facts sufficient to establish any inaccuracy, incompleteness, or misrepresentation."). As a result, the court recognized no obligation by the defendants to disclose additional information. *Id.* at 569-70. Here, by contrast, Plaintiffs have alleged that Defendants disclosed the favorable results of the Phase 2 trial to the virtual exclusion of the unfavorable results. Moreover, Plaintiffs have alleged the specific efficacy and safety issues identified in the Phase 2 study that Defendants failed to disclose before July 29, 2008. ¶65. Hence, even under the holding of *Adolor*, additional disclosure was required beyond what Defendants discussed on June 17, 2008.

Similarly, in *Padnes v. Scios Nova, Inc.*, No. Civ. 95-1693 MHP, 1996 WL 539711 (N.D. Cal. Sept. 18, 1996), the plaintiffs alleged that the defendants "should have disclosed details of the study which they characterize as design defects." *Id.* at *5. They did not allege the circumstances that prevail here, in which Defendants failed to disclose the unfavorable ***results*** of a completed study. For that reason, *Padnes* is not dispositive of the result here.

Finally, even if the literal truth of the June 17, 2008 press release were the question before the Court, Defendants' argument presents a textbook case of a disputed issue of fact that the Court should resolve in Plaintiffs' favor on a motion to dismiss. *See, e.g.*, *DeBose v. FedEx Corp.*, No. 08 Civ. 07042(AKH), 2009 WL 1542572, at *1 (S.D.N.Y. June 2, 2009) ("When considering a motion to dismiss for failure to state a claim, pursuant to Fed. R. Civ. P. 12(b)(6), a court must accept as true all factual allegations of the complaint, draw all reasonable inferences in the plaintiff's favor, and determine whether the complaint contains 'enough facts to state a claim to relief that is plausible on its face.'") (quoting *Twombly*, 127 S. Ct. at 1974)); *OSI Pharms.*, No. 2:04-CV-5505 (JS) (WDW), slip op. at 21 ("the veracity of the statements is a disputed issue of fact that may not be appropriately

decided in favor of Defendants at this stage of the proceedings"); *In re Keyspan Corp. Sec. Litig.*, No. 01 CV 5852 (ARR), 2003 WL 21981806, at *15 (E.D.N.Y. July 30, 2003) ("More fundamentally, defendants' arguments misapprehend the nature of a motion to dismiss. Even though this is an action for securities fraud, the court . . . must not draw factual inferences in favor of defendants."); *In re Cell Pathways, Inc. Sec. Litig.*, No. 99-725, 2000 WL 805221, at *8 (E.D. Pa. June 20, 2000) ("At this stage in the proceedings, once again, it would have been inappropriate for this Court to dismiss the Complaint based merely on CPI's vehement insistence on their version of contested issues in this case.").

Therefore, the Court may not resolve disputed issues of fact on this motion to dismiss.

5. Elan's Misrepresentations and Omissions Are Not Protected by the Safe Harbor for Forward-Looking Statements

Defendants argue that their statements are protected by the PSLRA's "safe harbor" provision. Def. Mem. at 44-46. Under 15 U.S.C. §78u-5(c)(1), certain persons "shall not be liable with respect to any forward-looking statement, whether written or oral, if and to the extent that (A) the forward-looking statement is – (i) identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement; or (ii) immaterial. . . ." Under §78u-5(c)(1)(B), the safe harbor does not apply if the plaintiff proves that the forward-looking statement "was made with actual knowledge." Defendants are incorrect that their misrepresentations and omissions are protected by the safe harbor.

The safe harbor extends only to forward-looking statements, not statements of current or historical fact. *See In re Veeco Instruments, Inc. Sec. Litig.*, 235 F.R.D. 220, 236 (S.D.N.Y. 2006) (safe harbor does not protect representations about "current or historical performance"). "A forward-looking statement is one whose truth or falsity cannot be determined until after the

statement has been made." *Viropharma*, 2003 WL 1824914, at *7. Specifically, the PSLRA defines a forward-looking statement as follows:

> (1) Forward-looking statement
>
> The term "forward-looking statement" means--
>
> (A) a statement containing a projection of revenues, income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items;
>
> (B) a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer;
>
> (C) a statement of future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management or in the results of operations included pursuant to the rules and regulations of the Commission;
>
> (D) any statement of the assumptions underlying or relating to any statement described in subparagraph (A), (B), or (C);
>
> (E) any report issued by an outside reviewer retained by an issuer, to the extent that the report assesses a forward-looking statement made by the issuer; or
>
> (F) a statement containing a projection or estimate of such other items as may be specified by rule or regulation of the Commission.

15 U.S.C. §78u-5(i)(1). *See also Darquea v. Jarden Corp.*, No. 06 CV 0722(CLB), 2007 WL 1610146, at *7 (S.D.N.Y. May 31, 2007) ("'It is well recognized that even when an allegedly false statement has both a forward-looking aspect and an aspect that encompasses a representation of present fact, the safe harbor provision of the PSLRA does not apply.'") (quoting *In Re AOL Time Warner, Inc., Sec. & ERISA Litig.*, 381 F. Supp. 2d. 192, 221 (S.D.N.Y. 2004)).

Because the statements and omissions Plaintiffs allege on May 21, 2007, July 26, 2007, and May 1, 2008 are historical (*see* ¶¶39, 43-44, 46-47), the safe harbor does not apply. Before the Class Period, Defendants represented that they would proceed directly to Phase 3 clinical trials only if the Phase 2 data they reviewed upon their interim look satisfied certain "very specific criteria" they had agreed upon with Wyeth, and were "spectacular," "very meaningful," and "strong." *See* ¶¶36-37.

When the Companies announced, on May 21, 2007, that they were proceeding to Phase 3 clinical trials, and that they were doing so at least in part based upon their earlier interim look at the Phase 2 data (*see* ¶39), they failed to disclose, as a matter of ***historical*** fact, that the interim look revealed negative safety and efficacy results and did not satisfy the Companies' "very specific criteria." *See also* ¶¶44, 46-47. For that reason, the safe harbor does not apply. *See* ¶43; *see also Veeco*, 235 F.R.D. at 236.

Nor does the safe harbor protect the June 17, 2008 press release, announcing selective results of the Phase 2 clinical trial. Defendants contend that the analysis presented in the release was "preliminary," subject to "further analysis," and therefore forward looking. *See* Def. Mem. at 46. Defendants do not dispute, however, that the Phase 2 testing itself was complete, and that the data was available to Defendants at the time of the press release. *See*, *e.g.*, Def. Mem. at 3 (referring to the Companies' June 17, 2008 press release as "disclosing the 'top-line' results of the ***completed*** Phase II trial"). Indeed, the study was completed in April 2008, two months before the release was issued. ¶¶11, 33, 84.

More importantly, the statements Plaintiffs allege are misleading – concerning the safety and efficacy of bapineuzumab (*see* ¶52) – do not even remotely fall within the definition of forward-looking statements in the PSLRA. As set forth above, forward-looking statements include financial projections, statements of the plans and objectives of management for future operations, statements of future economic performance, and any statement of the assumptions for any of the foregoing. *See* 15 U.S.C. §77z-2(h)(i)(1). Defendants' statements concerning the results of a clinical drug study are not forward-looking statements entitled to protection under the statutory safe harbor. *See*, *e.g.*, *In re Regeneron Pharms., Inc. Sec. Litig.*, No. 03 Civ. 3111 RWS, 2005 WL 225288, at *13 (S.D.N.Y. Feb. 1, 2005) (concluding that the safe harbor does not apply, and stating: "The Defendants'

statements that Plaintiffs allege are false and misleading involve representations of present or historical facts concerning, among other things, the effectiveness, safety, and tolerability of AXOKINE.").

Even if the misstatements at issue were forward looking, the safe harbor would still not apply because Plaintiffs have alleged that the misstatements were made with knowledge that they were false and misleading. *See, e.g., Rombach v. Chang*, 355 F.3d 164, 173 (2d Cir. 2004) ("'The doctrine of bespeaks caution provides no protection to someone who warns his hiking companion to walk slowly because there might be a ditch ahead when he knows with near certainty that the Grand Canyon lies one foot away.'") (quoting *In re Prudential Secs. Inc. P'ships Litig.*, 930 F.Supp. 68, 72 (S.D.N.Y. 1996)); *Regeneron*, 2005 WL 225288, at *13 ("[T]he safe harbor provision does not protect a statement made with 'actual knowledge' that it was false and misleading. 15 U.S.C. §78u-5(c)(1)(B)."). As discussed in the Statement of Facts above, as well as the scienter section that follows, Plaintiffs have alleged that Defendants acted with such knowledge.

Finally, Defendants claim that their alleged statements and omissions were protected by the PSLRA safe harbor because they used "warnings" that constituted "meaningful cautionary statements." Def. Mem. at 45-46. Nothing in the boilerplate language Defendants cite about "risks and uncertainties" warned the public about the known historical failure of bapineuzumab to satisfy the Companies' own criteria for success or the actual, negative results of the completed study. *See* Def. Mem. at 45, 46; *Irvine v. ImClone Sys., Inc.*, No. 02 Civ. 109 RO, at *1 (S.D.N.Y. June 4, 2003) (boilerplate disclosures inadequate to trigger protections of PSLRA safe harbor) (citing *In re Amylin Pharms., Inc. Sec. Litig.*, No. 01CV1455BTM(NLS), 2002 WL 31520051, at *9 (S.D. Cal. Oct. 10, 2002)); *Viropharma*, 2003 WL 1824914, at *8 ("The language that the Defendants cite as cautionary is verbose, and more importantly it falls far short of advising investors about an specific risks.");

Cell Pathways, 2000 WL 805221, at *11 ("to the extent that the challenged statements were accompanied by cautionary language, such warnings, taking Plaintiffs' allegations as true, were insufficient in light of CPI's knowledge at the time the statements were made that the risks had already materialized").

C. Plaintiffs Adequately Allege Scienter

To state a claim under §10(b) and Rule 10b-5, a plaintiff must allege facts providing a strong inference that the defendants acted with scienter, *i.e.*, a mental state embracing intent to deceive, manipulate or defraud. *See ECA, Local 134 IBEW Joint Pension Trust of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 198 (2d Cir. 2009). As the Supreme Court explained in *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308 (2007), "[t]he inference that the defendant acted with scienter need not be irrefutable . . . or even the 'most plausible of competing inferences,'" but merely "at least as compelling as any opposing inference one could draw from the facts alleged" (551 U.S. at 324), meaning that a tie is sufficient to avoid dismissal. *See, e.g.*, *Heller v. Goldin Restructuring Fund, L.P.*, 590 F. Supp. 2d 603, 620, n.14 (S.D.N.Y. 2008) (holding that "*Tellabs* clearly stands for the proposition that, if an 'inference of non fraudulent intent is equally permissible as any inference of fraudulent intent,' the complaint is properly pleaded") (citation omitted).

In the Second Circuit, a strong inference of scienter may be satisfied by either: (i) alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness; or (ii) alleging facts which demonstrate that defendants had motive and opportunity to commit fraud. *See ECA*, 553 F.3d at 198; *Scholastic*, 252 F.3d at 74. "The inquiry . . . is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation scrutinized in isolation, meets that standard." *Tellabs*, 551 U.S. at 322-23 (emphasis in original); *ECA*, 553 F.3d at 198 (courts must consider "all facts alleged, taken collectively"). Taking into account plausible opposing inferences, a court should find the complaint to sufficiently allege

scienter where "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324; *see also Veeco*, 235 F.R.D. at 231 ("'Although speculation and conclusory allegations will not suffice, neither do we require 'great specificity' provided the plaintiff alleges enough facts to support 'a strong inference of fraudulent intent.'") (quoting *In re Geopharma, Inc. Sec. Litig.*, 411 F. Supp. 2d 434, 440-41 (S.D.N.Y. 2006)).

The Second Circuit has identified "[a]t least four circumstances [that] may give rise to a strong inference of the requisite scienter: where the complaint sufficiently alleges that the defendants"

> (1) "benefitted in a concrete and personal way from the purported fraud"; (2) "engaged in deliberately illegal behavior"; (3) "knew facts or had access to information suggesting that their public statements were not accurate"; or (4) "failed to check information they had a duty to monitor."

ECA, 553 F.3d at 199 (quoting *Novak*, 216 F.3d at 311). The Complaint specifically alleges how Defendants knew facts or had access to information suggesting that their public statements were not accurate.[20]

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[20] Oddly, Defendants devote more than three pages of their memorandum to rebutting a motive-and-opportunity argument that Plaintiffs do not make. *See* Def. Mem. at 47-50. Plaintiffs base their allegations of scienter on Defendants' conscious misbehavior or recklessness. *See* ¶¶83-88; *see also Tellabs*, 551 U.S. at 325 (plaintiff need not allege motive to plead scienter; "the significance that can be ascribed to an allegation of motive, or lack thereof, depends on the entirety of the complaint").

1. The Complaint Alleges Facts Constituting Strong Circumstantial Evidence of Conscious Misbehavior or Recklessness

a. Defendants Knew Facts or Had Access to Information Suggesting that Their Public Statements Were Not Accurate

There can be no legitimate dispute that Defendants knew the interim and final results of the Phase 2 study of bapineuzumab when they made the misrepresentations at issue. Elan, along with Wyeth, conducted the study. ¶¶5, 32. On May 21, 2007, Elan and Wyeth announced that they were initiating Phase 3 trials based, in large part, on their analyses of the interim data. ¶39. As such, Defendants were necessarily aware of the interim results of the study. The Phase 2 study was completed in April 2008 and Defendants published their favorable and misleading version of the complete study results in a June 17, 2008 press release. ¶¶11, 13. Clearly, Defendants must have been in possession of the complete study results in order to publish them. Indeed, Defendants do not deny that they were aware of the interim and then final study results during the Class Period.

Plaintiffs contend that scienter has been properly alleged because Defendants "'knew facts or had access to information suggesting that their public statements were not accurate.'" *ECA*, 553 F.3d at 199. Given the undisputed fact that Defendants knew or had access to the study results during the Class Period, the only remaining question is whether those results suggested that their public statements were not accurate. They did.

With regard to the interim results, Defendants informed investors that they would proceed to Phase 3 studies only if the interim results met specific, objective criteria that Elan and Wyeth had established. Then, Defendants told investors that they were initiating Phase 3 studies in part based upon the interim results. ¶¶6, 39. Together, these statements unequivocally informed investors that the study results had satisfied the objective criteria of the interim review. Defendants knew that this was not true, that the interim results failed to establish the superiority of bapineuzumab over placebo

using the ADAS-cog and DAD tests that Elan and Wyeth agreed to before the interim results were known. ¶34. Defendants' knowledge that the interim results failed to meet the established criteria clearly "suggest[ed] that their public statements were not accurate" (*ECA*, 553 F.3d at 199), and establishes scienter.

The full results of the Phase 2 study similarly suggested that Defendants' June 17, 2008 press release was inaccurate and misleading. Defendants' press release contained the cherry-picked, favorable efficacy results of the study. ¶50. These results drove Elan's ADR price up 10% in one day and elicited cheers from analysts. ¶¶51, 53-56. When the full results of the study were finally disclosed – results which called into question not only the effectiveness of the drug but also its safety – the price of Elan's ADRs plummeted 42% in one day and prompted a strongly negative reaction from analysts, one of whom stated that "enough information was revealed to suggest that the Phase II results could be completely invalid." ¶¶66, 68. The overwhelmingly positive reaction to Defendants' press release concerning the study results and the equally negative reaction when the full-study results were disclosed graphically demonstrate that the press release did not accurately portray the results of the study. Because Defendants were indisputably in possession of the full-study results, which suggested that the June 17, 2008 press release was misleading, scienter has been properly established.

Unable to deny their knowledge of the interim and complete study results, Defendants instead argue that they had innocent reasons for withholding the information at issue, to wit:

> Elan and Wyeth did not comment on the data from the interim review of the Phase II results in their May 21, 2007 press release because the trial was ongoing and remained blinded; disclosing the data would have compromised the integrity of the trial, to the detriment of Elan and Wyeth, their investors, and patients. . . . The motivation for not including the detailed results of the Phase II trial in the June 17, 2008 press release was the embargo imposed by ICAD . . . .

Def. Mem. at 47. To begin with, both of these arguments rely upon supposed facts that are not alleged in the Complaint, and thus should not be considered in this proceeding. *See Tellabs*, 551 U.S. at 322. Further, neither of Defendants' excuses entitled them to mislead investors.

Defendants fail to explain how disclosing that the failure of the study to satisfy the criteria of the interim review would have compromised the blinded nature of the study. During the interim review, only a very limited number of people accessed the data to see who was taking the drug and who was taking placebo. ¶37. After the interim review, the trial continued in a blinded fashion, with neither the patients nor the doctors in the study the wiser. *Id*. Although Defendants were among those few people who knew that bapineuzumab was not outperforming placebo, they elected to speak to investors and convey that the interim review had met Elan's objective criteria. Apparently, Defendants would have the Court believe that these positive representations would not compromise the blinding of the study, but disclosure of the truth somehow would. In fact, whether or not Defendants disclosed the truth about the interim review results, the study would have been able to continue with neither doctors, patients, nor even most of the personnel at Elan and Wyeth knowing who was receiving the drug (the purpose of blinding). In any event, once the study was complete in April of 2008, the study was unblinded in order to ascertain how bapineuzumab had performed relative to placebo. ¶50. Accordingly, after April 2008, there was no blinding to compromise.

The supposed embargo by ICAD of certain information regarding the study is similarly irrelevant because, even if such an embargo existed, it did not obligate Defendants to issue the June 17, 2008 press release regarding the study. Defendants could have chosen to remain silent regarding the results of the study and disclose all of the results for the first time at ICAD. By choosing to speak about the study results, Defendants obligated themselves to disclose all material information

necessary to avoid misleading investors. *Time Warner*, 9 F.3d at 268 ("[a] duty to disclose arises whenever secret information renders prior public statements materially misleading").

To the extent that Defendants ask the Court to weigh the inferences raised by allegations of the Complaint against the inferences raised by Defendants' outside-the-pleadings arguments, it need not do so for the simple reason that they are in no way inconsistent. As set forth above, Plaintiffs contend that scienter is established because Defendants knew or had access to the interim and final results of the Phase 2 study, and those results suggested that Defendants' statements were misleading. Assuming this to be true (and Defendants do not dispute their knowledge of the Phase 2 results), Defendants' could ***also*** have had some concerns regarding the blinding of the study and the supposed ICAD embargo. Defendants' knowledge of the study results, and the fact that they rendered their statements false and misleading, is in no way inconsistent with the arguments about blinding or a purported ICAD embargo. Because Defendants' excuses in no way negate their knowledge of the study results or the misleading nature of their statements in light of those results, they offer Defendants no shelter.

This case is very different from the case law on which Defendants rely. For example, in *Cozzarelli v. Inspire Pharmaceuticals, Inc.*, 549 F.3d 618 (4th Cir. 2008) (*see* Def. Mem. at 47), the plaintiffs alleged that the defendants misled the public about the likelihood that a clinical trial of a drug for dry eye disease would be successful. 549 F.3d at 622. Plaintiffs based their claim on the defendants' withholding information about the clinical endpoints of the trial, and their use of the term "corneal staining" instead of "corneal clearing" in a public statement. *Id.* The court found that the plaintiffs had not sufficiently alleged scienter because the defendants had a legitimate business reason for not revealing details about the trial – protecting their competitive interests (*id.* at 626, 628) – and because the terms "corneal staining" and "corneal clearing" were "more or less

interchangeable – or at least interchangeable enough to dispel a strong inference of fraud." *Id.* at 626-27. Finding that "plaintiffs ha[d] not alleged the existence of any internal documents . . . or other direct statements contradicting the inference that defendants acted with a lawful intent based on their competitive interests" (*id.* at 626), the court dismissed the case for lack of scienter. *Id.* at 628.

Here, by contrast, Plaintiffs ***have*** identified "direct statements contradicting the inference that defendants acted with a lawful intent." *Id.* at 626. That is, Defendants represented that they would start Phase 3 clinical trials only if certain conditions came to pass, yet started those trials even though those conditions did ***not*** come to pass – without ever informing the public of the change. In other words, they created and perpetuated a misunderstanding among the public that they chose not to correct until it became unavoidable. Moreover, although not necessary in order to plead scienter, Plaintiffs have alleged a plausible reason for Defendants to do so: by postponing the truth about the results of the interim look for as long as possible, Defendants enhanced the likelihood that they would be able to fully enroll patients in the Phase 3 clinical trials. ¶87. As Elan's President, Carlos Paya, later acknowledged, the Company's "number one focus" was to finish the Phase 3 studies "as quickly as we can." *Id.* As the Complaint alleges: "Accordingly, the longer defendants could maintain the illusion of strong and spectacular Phase 2 Study results, the faster the Phase 3 studies could enroll and, defendants hoped, generate positive results."[21] *Id.*

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[21] Addressing motive and opportunity, Defendants argue that Plaintiffs' allegation that Defendants were attempting to expedite the enrollment of the Phase 3 clinical trial "must fail because scienter requires an intent to deceive the plaintiffs, not some third party" – doctors and patients. Def. Mem. at 50. Because Plaintiffs allege conscious misbehavior or recklessness to establish scienter, not motive and opportunity, Defendants' argument is irrelevant. Plaintiffs' allegation that Defendants were attempting to expedite the enrollment of the Phase 3 clinical trial speaks to the plausibility of Plaintiffs' allegations, not to Defendants' motivation (for purposes of establishing scienter). *See Tellabs*, 551 U.S. at 324 ("[t]he inference that the defendant acted with

Moreover, this is not a case, such as those that Defendants rely upon (*see* Def. Mem. at 52), in which the court found the most likely inference to be that the defendants honestly believed the information they issued to the public. *See In re AstraZeneca Sec. Litig.*, 559 F. Supp. 2d 453, 470-71 (S.D.N.Y. 2008) (relying on the defendants' "honest belief" and "honest analysis"); *Johnson v. Pozen Inc.*, No. 1:07CV599, 2009 WL 426235, at *22 (M.D.N.C. Feb. 19, 2009) ("It is more compelling . . . to infer that Defendants . . . honestly believed that the positive results would not pose a barrier to approval in August 2007."). Nor is this a case where "the motive for the alleged omission can be attributed to nothing more than a difference of scientific opinion about the importance and interpretation of aspects of complex scientific data." Def. Mem. at 52 (citing *In re Biogen*, 179 F.R.D. 25, 38 (D. Mass. 1997); *In re Medimmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md. 1995); *Padnes*, 1996 WL 539711, at *5).

Instead, this is a case in which the Defendants made a very specific representation – that they would not progress to Phase 3 clinical trial unless certain "very specific criteria" were satisfied – and then progressed to Phase 3 ***in the absence of those criteria being satisfied, and without so informing the public***. Further, Defendants selectively released the positive results of the study after it was complete while withholding virtually all of the negative results of the study. These are willful omissions that are actionable under the federal securities laws.[22]

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scienter need not be irrefutable . . . or even the 'most plausible of competing inferences,'" but merely "at least as compelling as any opposing inference one could draw from the facts alleged"). Finally, Defendants' suggestion that, as a matter of law, they could not be motivated to deceive study patients ***and*** shareholders finds no support in the law. *See, e.g., Roth v. Aon Corp.*, No. 04-c-6835, 2008 WL 656069, at *10 (N.D. Ill. Mar. 7, 2008) ("Defendants failed to account for the true nature and magnitude of Aon's contingent commission practices, because they knew that such a disclosure would negatively impact the company and its clients.")

[22] Defendants' suggestion that Johnson & Johnson's purchase of a 51% interest in Elan's 50% share of the Alzheimer's Immunotherapy Program in 2009 for approximately $885 million somehow

b. The Individual Defendants Are Presumed to Have Knowledge of the Falsity of Their Misrepresentations and Omissions

As set forth above, Elan conducted the Phase 2 study at issue and thus knew the results of that study. Defendant Martin spoke about the results of the study and was thus either aware of the results or reckless to speak in the absence of such knowledge. ¶46. Furthermore, even if the Individual Defendants did not have actual knowledge of the falsity of their representations, they are presumed to have that knowledge because the FDA-approval process for bapineuzumab goes to Elan's "core operations." As the court explained in *In re Atlas Air Worldwide Holdings, Inc. Securities Litigation*, 324 F. Supp. 2d 474 (S.D.N.Y. 2004), "When a plaintiff has adequately alleged that the defendant made false or misleading statements, the fact that those statements concerned the core operations of the company supports the inference that the defendant knew or should have known the statements were false when made." *Id*. at 489. Indeed:

> if facts that contradict a high-level officer's public statements were available when the statements were made, it is reasonable to conclude that the speaker had intimate knowledge of those facts or should have known of them. Accordingly, ***if a plaintiff can plead that a defendant made false or misleading statements when contradictory facts of critical importance to the company either were apparent, or should have been apparent, an inference arises that high-level officers and directors had knowledge of those facts by virtue of their positions with the company***.

Id. at 489; *see also Viropharma*, 2003 WL 1824917, at *9 ("[B]ecause Pleconaril was Viropharma's leading product and Defendants were the highest ranking member of the company, it can be assumed that Defendants were aware of these facts.").

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validates their version of events is illogical. *See* Def. Mem. at 1, 27. Not only are these facts found nowhere in the Complaint, but if bapineuzumab had been as "spectacular" as Defendants suggested throughout the Class Period, when analysts thought the drug would be worth $4-5 billion in annual revenue, presumably Johnson & Johnson would have paid correspondingly more for the interest they acquired.

For example, in *In re Forest Laboratories Securities Litigation*, No. 05 Civ. 2827(RMB), 2006 WL 5616712 (S.D.N.Y. July 21, 2006), the defendants falsely represented, *inter alia*, that the antidepressants Lexapro and Celexa – both manufactured by Forest Laboratories – were different from one another, when in fact they were essentially the same. *Id.* at *2-*3. The court held that "knowledge of (the similarities and difference between) Celexa and Lexapro goes to Forest's core business operations and is, therefore, presumed by Defendants." *Id.* at *10.

There can be no serious question that the development of bapineuzumab – including the process for taking an interim look at the Phase 2 data (about which both Individual Defendants made specific representations during the Class Period)[23] – goes to Elan's core business operations. Elan is a neuroscience-based biotechnology company that develops pharmaceutical products. ¶2. As the Complaint alleges, bapineuzumab had the potential to be the "biggest drug of all time" and, according to analysts, could have generated upwards of $4-5 billion in revenue per year. ¶85. In comparison, Elan's total revenue in 2007 was $759 million. *Id.* As the Associated Press stated before the end of the Class Period, "[w]ith an effective treatment for Alzheimer's being one of the holy grails of the pharmaceutical world, the rewards for Elan for bringing a successful drug to market would be incalculable." *Id.* Accordingly, financial analysts reported that "bapineuzumab is the stock-moving issue" for Elan and, more succinctly, "it's all about bap." *Id.*

Indeed, the success of bapineuzumab was all the more important to Defendants given the problems Elan was confronting during the Class Period. First, Elan's biggest selling product, Tysabri, had been removed from the market in February 2005 after two patients taking it died from a rare neurological disorder. ¶¶2, 85. It was back on the market as of September 2006, but only

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[23] *See, e.g.*, ¶¶37, 44, 46.

pursuant to a rigorous program to monitor the drug for further side effects. ¶2. By the start of the Class Period, sales of Tysabri had only slowly begun to recover. Second, the sales of a number of Elan's other drugs were plummeting due to generic competition. ¶¶2, 85. For example, the FDA approved a generic version of Maxipine, Elan's treatment for pneumonia, in June of 2007, precipitating a $52.2 million write-off by Elan. ¶85. Thus, Defendants were pinning their hopes for future profitability largely on bapineuzumab. *See In re Bristol Myers Squibb Co. Sec. Litig.*, 586 F. Supp. 2d 148, 168 (S.D.N.Y. 2008) (inference of scienter "easily drawn" given defendants' "own statements show[ing] how critical maintaining Plavix exclusivity was to the Company's profitability.").

The Individual Defendants cannot, therefore, make any credible argument that bapineuzumab did not, during the Class Period, go to the "core" of their business. Consequently, Defendants' knowledge of the falsity of their statements and omissions would be presumed even if Plaintiffs had not alleged facts demonstrating their actual knowledge of that falsity, which they have.

D. The Complaint Adequately Alleges the Individual Defendants' Control Person Liability Under §20(a) of the Exchange Act

In a single, perfunctory paragraph, Defendants contend that Plaintiffs' "control person" claims against the Individual Defendants under Section 20(a) of the Exchange Act, 15 U.S.C. §78t(a), fail because Plaintiffs have purportedly failed to allege: (1) an underlying violation of the securities laws; and (2) culpable participation by the Individual Defendants. Def. Mem. at 53. Defendants are incorrect.

First, as discussed above in detail, Plaintiffs have established a primary violation by Elan.

Second, the Second Circuit "has not defined what is meant by the requirement that a controlling entity be a 'culpable participant.'" *Pension Comm. of the U. of Montreal Pension Plan v. Banc of Am. Sec., LLC*, 592 F. Supp. 2d 608, 636 n.192 (S.D.N.Y. 2009). "[D]istrict courts in this

Circuit differ as to whether a plaintiff seeking to impose control person liability under Section 20(a) for Exchange Act liability must prove culpable participation by the putative control person in order to withstand a motion to dismiss." *In re Parmalat Sec. Litig.*, 599 F. Supp. 2d 535, 537 (S.D.N.Y. 2009). *See, e.g., In re LaBranche Sec. Litig.*, 405 F. Supp. 2d 333, 363-64 (S.D.N.Y. 2005) ("[i]n order to state a Section 20(a) claim, no . . . particularized allegations [of culpable participation] are required); *In re WorldCom, Inc. Sec. Litig.*, 294 F. Supp. 2d 392, 420 n.18 (S.D.N.Y. 2003) ("Congress . . . has imposed a heightened pleading standard for a Section 10(b) claim but not for a Section 20(a) claim. Indeed, if Section 20(a) contained the requirement that scienter be pleaded and proved, there would be little purpose served by Section 20(a) since a defendant who acts with scienter is liable under Section 10(b)."); *In re Initial Pub. Offering Sec. Litig.*, 241 F. Supp. 2d 281, 395 (S.D.N.Y. 2003) (holding that "Section 20(a) has no scienter element," and reasoning that Congress merely intended to hold a control person liable to the same extent as the person controlled unless the controlling person acted in good faith") (citations omitted). *But see Ellison v. Am. Image Motor Co. Inc.*, 36 F. Supp. 2d 628, 637 (S.D.N.Y. 1999) (requiring "particularized facts as to the controlling person's culpable participation in the fraud perpetrated by the controlled person").

Whatever the definition of "culpable participation," Plaintiffs have satisfied it. The Complaint alleges that both Individual Defendants held positions of authority and control at Elan – Martin was Elan's President and CEO at all relevant times (¶25), and Ekman was Elan's President of Research and Development during the Class Period until December 31, 2007, and was a member of the Board of Directors and Chairman of the Science and Technology Committee of the Board throughout the Class Period (¶26) – and that they actively participated in the fraud. Both articulated the conditions under which the Companies would proceed to Phase 3 testing, both were aware of the results of the interim look at the Phase 2 data, as well as the full Phase 2 results, and both uttered

materially false or misleading statements. *See, e.g.*, ¶¶37, 46-47, 50, 52. This is more than sufficient to allege control person liability. *See, e.g., Tower Auto*, 483 F. Supp. 2d at 351 ("Plaintiffs' assertion that Defendants exerted control by virtue of their senior positions within the company combined with the scienter allegations scattered throughout the Complaint meet the bar required by Rule 8's notice pleading standard.").

E. If the Court finds that the Complaint Is Deficient in any Respect, Plaintiffs Should Be Granted Leave to Move to Amend

Plaintiffs believe that they have more than adequately stated claims against all Defendants. However, in the event the Court determines the Complaint is deficient in any respect, Plaintiffs respectfully request an opportunity to move for leave to amend in accordance with Fed. R. Civ. P. 15(a) ("leave shall be freely given when justice so requires"). *See In re Amaranth Natural Gas Commodities Litig.*, 587 F. Supp. 2d 513, 548 (S.D.N.Y. 2008) ("'it is the usual practice upon granting a motion to dismiss to allow leave to replead.'") (quoting *Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F.2d 42, 48 (2d Cir. 1991)).

Because Plaintiffs have made no previous request to amend the Complaint, and this would be Plaintiffs' first opportunity to address any substantive defect in the Complaint identified by the Court, Plaintiffs should be permitted to do so.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court deny Defendants' motion to dismiss in its entirety.

DATED: February 16, 2010

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Lead Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on February 16, 2010, I caused the foregoing to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such public filing to all counsel registered to receive such notice.

/s/ Samuel H. Rudman
SAMUEL H. RUDMAN